Remarks

Prior to this amendment, claims 1-33 and 46-54 were pending in this application. New claims 55-57 are added. Claims 1-10, 23-33 and 46-54 are currently withdrawn. Support for new claims 55-57 can be found in the specification at least at page 14, line 24 through page 15, line 8.

No new matter has been added in this amendment. Unless specifically stated otherwise, none of these amendments are intended to limit the scope of any claim. After entry of this amendment, **claims 1-33 and 46-57 are pending** (of which claims 1-10, 23-33, and 46-54 are withdrawn).

Previously submitted documents

Applicants thank Examiner Leavitt for acknowledging the receipt of:

(i) the Declaration under 37 CFR 1.132, signed by Dr. Kamohara (filed on September 28, 2007);

(ii) the Declaration under 37 CFR 1.132, signed by Dr. Yoshimura (filed on September 19, 2007);

(iii) the Declaration For Patent Application, signed by Dr. Kamohara (filed on September 28, 2007);

(iv) the executed Consent of Assignee Under 37 CFR 1.497 regarding Inventorship, consenting to the addition of Dr. Kamohara as an inventor of the application (filed on September 19, 2007); and

(v) an unexecuted statement by Dr. Kamohara under CFR 1.497 (filed on September 19, 2007).

However, with regard to item (v), Applicants point out that a statement under CFR 1.497 signed by Dr. Kamohara was submitted with the Supplemental Amendment on September 28, 2007, along with the Declaration under 37 CFR 1.132 and the Declaration For Patent Application, both of which were signed by Dr. Kamohara, as discussed above. Moreover, the Patent Application Information Retrieval (PAIR) system acknowledges that a statement under CFR 1.497 signed by

Dr. Kamohara was submitted on September 28, 2007. Thus, Applicants respectfully submit that any executed documents not submitted with the Amendment and Response (Amendment) on September 19, 2007, were subsequently submitted with the Supplemental amendment on September 28, 2007.

Priority

Applicants thank Examiner Leavitt for acknowledging that claims 11-16 and 21-22 (with regard to the term "granulocyte-macrophage-colony stimulating factor" as recited in claim 13) claim priority from U.S. Provisional Application No. 60/363,734, filed March 12, 2002, and that claims 17 and 18 (with regard to the term "DDR-1 activating antibody" as recited in claim 17) claim priority from U.S. Provisional Application No. 60/419,179, filed October 16, 2002. However, the Applicants disagree that claim 19 also has an effective priority date of October 16, 2002, as it depends from claim 11 (not claim 17) and does not require a "DDR-1 activating antibody." Thus, Applicants respectfully request that the Office acknowledge the March 12, 2002 effective priority date of claim 19 in a subsequent communication.

Applicants also thank Examiner Leavitt for acknowledging that claim 20 (with regard to the term "CD40" ligand) claims priority from U.S. Provisional Application No. 60/419,179, filed October 16, 2002. Applicants note that claim 20 is directed to the use of CD40 (among other agents) to enhance monocyte or dendritic cell maturation from immature macrophage or immature dendritic cells. U.S. Provisional Application No. 60/380,978, filed May 15, 2002 clearly discloses that CD40 can be used to induce dendritic cell (DC) maturation (see pages 31 and 58). Thus, if claim 20 is amended in the future to be directed to the use of CD40 to induce maturation of dendritic cells only, Applicants submit that such an amended claim would have an effective priority date of May 15, 2002.

Statement under 37 CFR 1.497 Regarding Inventorship signed by Dr. Kamohara/Renewed Request for Addition of Inventor

The Office action states that the petition to change inventorship under 37 CFR 1.497 is defective because a statement under "37 CFR 1.497(d) covers the situation where Applicants file a PCT application with one inventive entity and ***before*** they enter national in the US [or ***before***

they give the USPTO an acceptable oath/declaration in that national phase entry process]." The Office action further states that "[t]his appears to be a Rule 48(a) situation where the applicant has presented a proper oath/declaration and now they want to change the inventorship. It is suggested that applicants should file a petition under 37 CFR 1.48(a) to change the inventorship" (Office action at page 5).

As suggested by the Office, Applicants submit herewith a Petition Under 37 CFR 1.48(a) Adding Erroneously Omitted Inventor in Non-Provisional Application executed by Dr. Kamohara. In addition, Applicants submit a Consent of Assignee Under 37 C.F.R. 1.48(a) Regarding Inventorship, executed by the Assignee. These documents supplement the new Declaration, signed by Dr. Yoshimura (submitted on September 19, 2007) and by Dr. Kamohara (submitted on September 28, 2007). A copy of the previously submitted (and executed) new Declaration is provided herewith for the Examiner's convenience. Applicants note that the processing fee required by §1.17(i) was submitted on September 19, 2007. However, if it is determined that an additional fee is required with regard to this Petition, please charge Deposit Account 02-4550.

Applicants hereby request that the United States Patent and Trademark Office (USPTO) enter these documents and that the inventorship for this application be corrected. Applicants also request that the USPTO issue a new filing receipt identifying Hidenobu Kamohara as an inventor in this application.

Notice of Non-Compliant Amendment

The Office action alleges that the comments regarding "5. Other (e.g., the amendment is unsigned or not signed in accordance with CFR 1.4): see attachment", submitted in the December 28, 2007 Response to the Notice of Non-Compliant Amendment, were not persuasive.

As discussed in Applicants' December 28, 2007 Response, the November 29, 2007 Notice of Non-Compliant Amendment did not indicate *which* document was unsigned, only that "the amendment is unsigned or not signed in accordance with CFR 1.4" (Notice on Non-Compliant Amendment; emphasis added). Thus, without further information, Applicants could

not surmise exactly which document the Office believed was submitted without the appropriate signature. The Office has now clarified that "the statement under 37 C.F.R. 1.497 regarding inventorship filed electronically via EFS on September 19, 2007 . . . has not been executed by Dr. Hidenobu Kamohara (see attached appendix)" (Office action at page 6).[1] As discussed above, the Statement under 37 C.F.R. 1.497 signed by Dr. Kamohara was, in fact, submitted on September 28, 2007 (well before the date of the Notice of Non-Compliant Amendment). In light of the prior submission of the executed Statement under 37 C.F.R. 1.497, Applicants respectfully submit that the Amendment submitted on September 19, 2007 and the Supplemental amendment submitted on September 28, 2007, were submitted in accordance with 37 CFR 1.4.

Withdrawal of Objection to Specification

Applicants thank Examiner Leavitt for withdrawing the objection of the specification.

Claim Rejections Maintained

Claim Rejections Under 35 U.S.C. §102(a)

Claims 11-16 and 21-22 continue to be rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Kamohara *et al.* (*FASEB J.* 2001 Dec;15(14):2727-6. Epub 2001 Oct 15) because the "statement submitted under 37 CFR 1.497 regarding inventorship is defective because a new inventor cannot be added under this Rule" (Office action at page 7). As discussed above, Applicants submit herewith

(i) Request to correct inventorship;

(ii) A Petition Under 37 CFR 1.48(a) Adding Erroneously Omitted Inventor in Non-Provisional Application executed by Hidenobu Kamohara M.D., Ph.D.;

(iii) Consent of Assignee Under 37 C.F.R. 1.48(a) Regarding Inventorship, executed by the Assignee; and

(iv) Declaration, signed by Dr. Yoshimura and by Dr. Kamohara.

Thus, Applicants submit that the requirements to add Dr. Kamohara as an inventor under 37 CFR 1.48(a) have been fulfilled.

[1] Applicants note that an appendix was not received with the Office action and is not available on PAIR.

As discussed in the Amendment submitted on September 19, 2007, a Declaration under 37 C.F.R. § 1.132 was submitted with the September 19, 2007 Amendment as evidence to overcome Kamohara *et al.* The Declaration states that co-authors T. Yoshimura and H. Kamohara are inventors of the subject matter claimed in the present application. The Declaration also states that the remaining co-authors, S. Yamashiro and C. Galligan, are not inventors of the present application. Thus, Kamohara *et al.* is a disclosure made by the applicants themselves. As such, it does not satisfy the requirement of § 102(a), which requires an anticipatory disclosure be made "before the invention thereof by the applicant." In view of the Petition Under 37 CFR 1.48(a) and the Declaration Under 37 C.F.R. § 1.132, Kamohara *et al.* is not available as prior art. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 11-19 and 20 continue to be rejected under 35 U.S.C. § 103(a) as allegedly being obvious in light of Kamohara *et al.* in combination with Lipford *et al.* (U.S. Pub. No. 2003/0148316, published August 7, 2003). As discussed above, Kamohara *et al.* is not available as prior art against the current application. The secondary reference, Lipford *et al.*, does not teach all the limitations of the claims. Lipford *et al.* discloses that DDR1 is expressed in plasmacytoid dendritic cells and that *DDR1 expression levels* may be elevated when these cells are incubated with immunostimulatory nucleic acids (Table 5c). Lipford *et al.* also discloses that plasmacytoid dendritic cells are generated by treatment with granulocyte-macrophage-colony stimulating factor (GM-CSF). However, Lipford *et al.* fails to specifically disclose the step of contacting an immature macrophage or an immature dendritic cell with an effective amount of a *DDR1-activating agent.*

The specification teaches that a DDR1 activating agent *stimulates DDR1* and that "[a]ctivation of DDR1 results in the recruitment and phosphorylation of intracellular signaling molecules, such as, but not limited to, molecules of the p38 MAP kinase pathway . . . Activation of DDR1 can be increased by contacting DDR1 with a DDR1 ligand or an agent that acts as an agonist of DDR1" (page 9, line 31 through page 10, line 8; see also page 14, line 24 through

page 15, line 8). As taught by the specification, "[e]xamples of DDR1 activating agents include DDR1 ligands, such as collagen, or other agents, such as an antibody, a small molecule, a chemical compound, a peptidomimetic or a protein" (page 9, lines 29-31). The specification does not teach that a DDR1 activating agent is GM-CSF or that it is an agent that increases DDR1 *expression levels* in order to induce maturation of the immature macrophage or the immature dendritic cell. Furthermore, the specification teaches that GM-CSF is an agent that induces DDR1 expression, not DDR1 signaling. Thus, Lipford *et al.* alone does not anticipate or render obvious claims 11-19 and 20, and this reference does not make up for the deficiencies of Kamohara *et al.* In light of the above discussion, Applicants respectfully request reconsideration and withdrawal of this rejection.

Conclusion

Based on the foregoing arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the number listed below.

Respectfully submitted,

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